REMARKS

The above-captioned patent application has been carefully reviewed in light of the non-final Office Action to which this Amendment is directed. The Examiner has rejected all pending Claims 2, 6-22, 56-59 and 62-71 on the basis of certain prior art. More specifically, the Examiner has rejected the pending claims under 35 USC 103(a) as being unpatentable over Miller, Muszak et al., or Carey et al., each previously cited by the Examiner, and further in view of Hamilton et al. (U.S. Patent No. 4,568,519). Applicants herein respectfully request reconsideration based on the following discussion.

Applicant gratefully acknowledges the interviews granted by Examiner Lyle Alexander to Applicant's representative, Peter J. Bilinski, on December 7 and 14, 2005. The subject matter of this amendment/response includes those discussed during the interview.

Prior to a discussion of the pending prior art rejection, Applicants would again like to relate the salient features of the present invention. The herein claimed incubator is used in a clinical analyzer and includes structure that is defined by respective first and second rings that are concentrically situated relative to each other. Each of the inner and outer rings includes respective first and second pluralities of circumferentially disposed sample element receiving areas. According to the specific embodiment described in the above-captioned application, the inner ring includes a pair of radially adjacent sample receiving area arrays while the outer ring includes a single circumferential array of sample element receiving areas. As such, each of the first and second pluralities of sample element receiving areas are radially adjacent to one another and are further disposed along a common horizontal plane.

The inner and outer rings are each rotatably driven, such as by a belt drive, to enable rotation about their axes, in either a clockwise or counterclockwise direction along the common horizontal plane. Moreover, the inner and outer rings can be driven (e.g., rotated) independently from one another. Each of the rings are provided on the common horizontal plane such that at least one shuttle mechanism provided

adjacent to the inner or the outer rings of the incubator can be utilized selectively to move sample elements (such as, for example, dry slide elements) in a radial direction between the sample element receiving areas of the outer ring and the inner ring.

More particularly and according to the present invention, the at least one shuttle mechanism allows any number of sample elements to be shifted within the confines of the incubator between adjacent planar sample element receiving areas. As such, separately disposed sample element shuttle mechanisms disposed at discrete circumferential locations or positions relative to the inner and/or outer ring permit any number of sample elements to be selectively shifted between different radial positions in either the inner and outer rings. This selective shifting of sample elements provides unique advantages in that greater throughput is realized for the clinical analyzer to which the incubator is used, as well as a more efficient means for the scheduling of test events, particularly wherein the outer ring includes at least one instrument for measuring a property of a sample and in which the inner ring includes at least one different instrument for measuring another property of the sample, each property requiring different protocols (times incubated prior to test) of the incubator.

For example, one shuttle mechanism can be used to allocate a sample element that has been loaded into the incubator into one of the sample element receiving areas of the outer ring wherein the sample element can be rotated a number of circumferential positions (N) about the axis of the ring and then the same or an circumferentially adjacent shuttle mechanism can be used to push the sample element into the inner ring, freeing the adjacent sample element receiving area of the inner ring so as to allow the receiving area to load another metered sample element and permitting the shuttled sample element to be moved (e.g., rotated) by the inner ring until the sample element is moved into alignment with a read station. Alternately, other sample elements can remain on the exterior or the outer ring, depending, for example, on the type of sample element used, the forms of tests required, etc.

As noted, there are a number of advantages in providing the above features and permitting planar radial and notational movement of the sample elements in the manner herein described. By providing a number of sample elements having different chemistries and having different test protocols, there are also correspondingly different incubation requirements (cycle times). Using the present incubator, a first sample element can be shuttled into the outer ring for potentiometric testing and a second sample element can then be shuttled into the incubator for colorimetric testing upon rotation of the outer ring to a circumferentially adjacent sample element receiving area. Subsequent rotation of the outer ring enables the second sample element to be relocated, such as by the same or another shuttle mechanism, between the radially adjacent sample receiving area of the outer ring planarly and a corresponding receiving area of the inner ring, while the potentiometric (first) element can remain in the outer ring. In the meantime, additional sample elements can be loaded into the incubator into "freed up" or empty sample receiving areas of the inner ring, effectively increasing throughput. Additionally, an IR wash or other module can be added to the interior of the inner ring, providing further versatility with another radially adjacent shuttle mechanism that can be used to move sample elements into and out of the module and between radially adjacent sample receiving areas of the inner and outer rings as the inner and outer rings of the incubator are caused to rotate about their respective axes.

A greater number of sample elements can be loaded into the incubator housing at any one time and handled appropriately wherein the synchronization of the ring/rotor assemblies can be preset, for example, by an offsetting to permit efficient transfer of sample elements between the concentric rotor assemblies and therefore to efficiently maintain and improve the test schedule of the clinical analyzer.

Turning to the cited art and as previously noted, Miller describes a twin rotor incubator assembly for a clinical analyzer. The incubator assembly that is described includes a pair of independently driven, vertically stacked rotors 52, 54 that are interconnected by means of an elevator assembly relative to a metering station. The rotors are not provided on a common horizontal plane. As sample elements are metered, the elements are brought into either of the vertically stacked rotors using a pusher blade. In order to move any of the sample elements between these stacked and offset rings, however, there must be a vertical component of movement in order to access the remaining rotor. That is and in order to move sample elements between the vertically stacked ring elements in order to "free up" space, for example in one of the rings, the slide element must first be removed from one of the rings, loaded onto the elevator assembly, raised or lowered, and then reloaded horizontally into the remaining ring. That is to say, the sample element receiving areas of the first and second rotors are not provided on a common horizontal plane and therefore movement of the slide elements between the slide element receiving areas of the rotors does not occur exclusively along a common horizontal plane. Because this reference fails to disclose a relationship between first and second pluralities of sample element receiving areas that would permit radial movement therebetween, it is not understood how this reference can anticipate the present invention.

Muszak et al. teaches the elevator assembly that is used by the incubator that is described by Miller. As such, this reference elevator fails to provide or suggest any structure or a resulting mechanism that is capable of radial transport along a common horizontal plane between radially adjacent sample element receiving areas that are disposed on coplanarly arranged inner and outer rings.

The remaining primary reference to Carey et al. describes an incubator assembly that is used to handle multiple assays in an immunoassay clinical analyzer. The incubator includes a housing having a single cuvette ring that includes a plurality of circumferential slots, each sized for receiving a cuvette. The cuvette ring is disposed above a magnet ring used in conjunction with a drive assembly 18 to drive the cuvette ring. The cuvette ring is driven radially so as to pass a plurality of

circumferentially arranged stations, including read stations. In addition, a number of other circumferentially disposed stations are positioned outside of the incubator housing as used to dispense reagents, wash fluids, and perform other assay reaction steps. The cuvettes are not moved to positions other than the cuvette ring during any read, aspirate or dispense operation utilizing the exterior disposed stations. This incubator also includes an elevator assembly, as described at col 18, lines 56-67, wherein a cuvette can be lifted from a slot to permit a new cuvette to be added to take a now empty slot in the cuvette ring. To that end, this reference is significantly different structurally from the claimed invention in that this reference fails to describe radially adjacent rings having sample element receiving areas wherein movement can be achieved between the rings along a horizontal plane.

The secondary reference to Hamilton et al. describes a slide distributor for the delivery and removal of slide elements from an incubator. See col. 1, lines 9-11. The slide distributor is defined by a single shuttle mechanism that is located outside of the incubator housing that can be used to either load or unload slide elements from an incubator. The advantage that is sought is that a slide can be unloaded and a new slide can be loaded into the incubator in a relatively short period of time (see col. 2, lines 1-9), facilitating the time that tests can be conducted in the incubator. The shuttle mechanism includes a pusher blade and a picker to enable the slide elements to be loaded and/or unloaded from the incubator.

Applicants wish to point out several features that distinguish the present invention from this latter reference. First and as noted above, Applicants do not claim to invent a shuttle mechanism for loading and unloading slide elements from an incubator. The teachings of the herein cited reference illustrate a single shuttle blade design that is used in conjunction with a single ring incubator. Hamilton et al. (U.S. Patent No. 4,568,519) provides a typical example of a shuttle mechanism. In that sense, such mechanisms are similarly described in Miller and Muszak et al., previously cited herein. A preconditioner is shown, but this preconditioner is part of a single station at a circumferential location. Therefore, the preconditioner is not in fact part of a circumferential <u>array</u> of sample element receiving areas. In fact, the

discussion of the patent relates that the incubator is designed as disclosed in U.S. Patent 4,296,069 to Smith et al. A copy of the Smith '069 patent is attached hereto for the Examiner's reference. The Smith incubator is defined by a single rotor mounted within a housing and includes a single plurality of slide holders 24 wherein slides are loaded according to a predetermined protocol, as the single rotor rotates. On the other hand, Applicants have devised a twin horizontal rotor design that can utilize at least one shuttle mechanism to shuttle slide elements either into the first plurality of slide element receiving areas, into the second plurality of slide element receiving areas and/or between the first and the second slide element receiving areas along the common horizontal plane. None of the prior art cited by the Examiner provides this structure and therefore it is not possible absent hindsight of the present invention to argue that Hamilton is the missing piece of the invention merely because movement is achieved in a horizontal plane. As noted, Miller and Muszak et al each also describe a shuttle mechanism, but fail to describe a twin rotor structure as presently claimed by Applicants wherein at least one shuttle mechanism can be used to selectively shuttle between each of the radially adjacent sample element receiving areas of the inner and outer rings.

In addition, there clearly is no indication, suggestion, or other inference of providing a number of discrete shuttle blade assemblies, each of the assemblies being disposed at unique circumferential positions, such as recited, for example, in Claim 64, in any of the cited prior art.

To that end, it is believed that a "*prima facie*" obviousness rejection cannot be maintained based on the cited art. The combination of the art as posited by the Examiner fails to provide the structure of the invention that is positively recited in independent Claim 62. None of the cited prior art, either singly or in combination, provides an incubator having an inner and an outer ring wherein the inner ring includes a first plurality of circumferentially disposed sample element receiving areas and the inner ring includes a second plurality of sample element receiving areas. As previously noted, each of the primary references to Muszak et al. and Miller define first and second pluralities of sample element receiving areas, but in

which the areas are not radially adjacent or at least in which movement cannot occur between the areas along a horizontal plane common to the sample element receiving areas. This latter feature is essential for the second drive mechanism of the claimed incubator of Claim 62. That is, the at least one second drive mechanism is used for selectively moving sample elements exclusively in a radial direction along the horizontal plane common to the first and second plurality of sample element receiving areas. Since Miller and Muszak et al. specifically require the rings be vertically stacked, the sample element receiving areas cannot be formed within a common horizontal plane as required by each of independent Claims 62 and 63. In addition, each of Muszak et al and Miller already utilize a shuttle mechanism as described by Hamilton et al. Yet in spite of having that capability, there is no teaching of a purely horizontal arrangement in spite of the shuttle mechanism/slide distributor capability. Hamilton et al does not appear to teach anything that is not already discussed or shown in Miller or Muszak et al. This latter reference shows a single rotor incubator design and therefore fails to show or suggest using two radial pluralities of circumferentially disposed sample element receiving areas. Therefore, Hamilton's application would appear to be redundant to the subject matter of the remaining cited art. None of the cited prior art describes a horizontal twin rotor design according to Claim 62. For example, Carey et al. is similarly flawed. Carey et al. fails to describe inner and outer rings, each including sample element receiving area arrays that are radially adjacent along a horizontal plane. This reference includes a pair of stacked rings, only one of which includes sample element receiving areas. Therefore, it is similarly clear that there is no radial movement between inner and outer rings since this design fails to include same. As a result, reliance on this reference also appears misplaced with regard to the present invention. For the foregoing reasons, it is believed that a prima facie obviousness rejection cannot be made regarding Claim 62.

Each of Claims 3, 6-22, 56-59, and 64-67 are believed allowable since these claims depend from Claim 62. Reconsideration is respectfully requested.

Independent Claim 63 recites a method of incubating and reading test sample elements using a sequential random incubator in a clinical analyzer, wherein the analyzer includes an inner ring and an outer ring, the outer ring having a first plurality of circumferentially disposed sample element receiving areas and the inner ring having a second plurality of circumferentially disposed sample element receiving areas in which each of the first and second pluralities are radially adjacent to one another on a common horizontal plane. As previously noted, none of Muszak et al, Miller, Carey et al. or Hamilton et al depicts this form of horizontal coplanar structure. The method steps further distinguish in that the steps that are recited include radially loading at least one sample element into an empty sample element receiving area as well as movement rotationally of at least one of the inner and outer rings along the horizontal plane. The claimed method requires the radial movement of at least one sample element between the first and second pluralities of sample element receiving areas along the common horizontal plane. This latter step is not remotely suggested or taught in any of the cited prior art since none of this prior art has the supporting structure to perform that movement. As previously noted, each of Miller and Muszak et al. clearly require that movement between sample element receiving areas of the twin rotors MUST occur by vertical movement via an elevator assembly between the two vertically stacked rotors. Hamilton et al also teaches movement in a single rotor assembly and therefore only relative to one plurality of circumferentially disposed sample element receiving areas. Carey et al. describes structure that includes only a single array of radially disposed sample element receiving areas. As such, no means is either described or suggested for radial movement between horizontally coplanar sample receiving areas. Therefore, features recited in Claim 63 are missing from this cited art that are not found or suggested, absent hindsight and significant structural changes to the cited references. Therefore, it is believed that a "*prima facie*" case of obviousness cannot be maintained with regard to this claim and this rejection should therefore be withdrawn.

Claims 68-71 have been canceled. The rejections with regard to these claims are therefore moot. Since no substantive amendments have been made to the claims, it is believed entry of the Amendment/Response is proper under 37 CFR §1.116.

In summary, it is believed the above-captioned patent application is now in an allowable condition and such allowance is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicants' representative at the telephone number below.

The Director is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

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